The Commonwealth of Massachusetts
Board of Registration in Pharmacy
Bureau of Health Professions Licensure
250 Washington Street, Boston, MA 02108-4619
Tel: 617-973-0960
Fax: 617-973-0980
TTY : 617-973-0988
Pharmacy.Admin@mass.gov

New Pharmacy Application Instructions

The following requirements pertain to any applicant seeking a new pharmacy license from the Board of Registration in Pharmacy (Board). Review 247 CMR for complete information regarding applicable regulations. If additional information is necessary, please contact the Board office.

***Non-resident pharmacy** licensure is not yet available. See here for details.

This application must be approved by the Board before the pharmacy can operate. **Submitted applications are only valid for 1 year. Retain a copy of the completed checklist, applications, and supporting documents for your records.**

Fees: A check or money order for the application fee and controlled substance registration must be payable to the ***Commonwealth of Massachusetts***.

Note: Do not send cash, foreign currency, or electronic funds transfers. There will be a $23 handling charge for returned checks. **Fees are non-refundable and non-transferable**.

To obtain a registration from the Drug Enforcement Administration (DEA), please contact them directly:

J.F.K. Federal Building
Drug Enforcement Administration
Room E400
15 New Sudbury Court
Boston, MA 02203-0131
(617) 557-2200

Retain copies of all documents for your records.
Do not submit checklist.

Checklist of Documents to be Submitted

DO NOT SUBMIT CHECKLIST

☐ A fully and properly completed, signed and notarized New Pharmacy Application (*see pages 4-6*) and associated **$525 fee**.

☐ Controlled Substance Registration (CSR) application and associated **$225 fee**. (*see page 7*)

☐ If applicable, submit a completed Petition for a Waiver for each regulation and section the facility is requesting to be waived at the new location.

☐ A list of all state(s) where the facility is licensed or registered.

☐ An official blueprint or certified architectural plans drawn to scale (*see page 13*).

☐ Hours of operation (*see page 12*)

☐ On a separate sheet of paper briefly describe the business model including any additional services the pharmacy will provide (e.g., compliance packaging, compounding, delivery, immunization, veterinary, long-term care, etc.).

☐ If proposing to locate within any Massachusetts healthcare facility, documentation of approval from the facility's licensing body(s) must be attached.

Ownership:

☐ If the facility is owned by an individual(s), provide the name of owner(s), address(es), and Social Security Number(s).

☐ If the facility is owned by a partnership, provide the partnership name, address, and FEIN number.

☐ If the facility is owned by a corporation, provide the corporation's name, address, FEIN number, state in which company is incorporated, names of corporate officers and their positions and addresses and either a copy of the:

- Articles of Organization, signed, and sealed by the Secretary of State if incorporated in Massachusetts; **or**
- Foreign Corporation Certificate, signed, and sealed by the Secretary of State pursuant to M.G.L. c.181, § 4 if incorporated in another state.

Sterile Compounding Pharmacy Checklist: (*in addition to the items listed above*)

☐ Attestation of Intent to Conduct Sterile Compounding signed by the MOR. (*see pages 10-11*)

☐ Certified blueprints of the compounding area(s).

☐ Sterile Compounding Pharmacy Compliance form for DRAFT sterile compounding regulations 247 CMR 17.00. (*see pages 14-15*)

Complex Non-Sterile Compounding Pharmacy Checklist: (*in addition to the items listed above*)

See definition of Complex Non-Sterile compounding here.

☐ Attestation of Intent to Conduct Complex Non-Sterile Compounding completed and signed by the MOR. (*see pages 8-9*)

☐ Certified blueprints of the dedicated compounding room(s).

Nuclear Pharmacy Checklist: (*in addition to the items listed above*)

☐ Certified blueprints of the compounding area(s).

☐ Documentation of MA Department of Public Health, Radiation Control Program (RCP) licensure.

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New Pharmacy Application

TO BE COMPLETED BY BOARD

CHECK $_____DATE_____

CHECK NO. _____RECEIPT NO. _____APP NO. _____

Demographic Information

Legal Name of Facility _____

All trade or business names ("D.B.A." names) _____

Tel. No. _____ E-mail _____

Street Address (physical address) _____

City/Town _____ State_____ Zip Code _____

FEIN No. _____ RCP License No. (nuclear pharmacy only): _____

Name of Proposed Manager of Record (MOR) _____

MOR MA License No. _____ MOR NABP Profile No. _____

MOR Social Security No. _____
***mandatory*

Name, phone number, and email address of the contact person for questions regarding this application:

Name_____

Tel. No. _____ E-mail _____

Suitability

For the applicant, MOR, or any owners and corporate officers, provide a list of any licenses/registrations/certifications in the United States or any country or foreign jurisdiction and the state/jurisdiction from which the license/registration/certification was originally issued. Include proof of standing from each state or jurisdiction. The verification must indicate the status of the license and any relevant disciplinary information.

Has the applicant, MOR, or any owner or corporate officer ever owned, operated, or held an interest in any facility licensed or registered in Massachusetts?
☐ Yes ☐ No *If yes, please provide all facilities' legal name(s) and license or registration number(s).*

Has the applicant, MOR, or any owner or corporate officer owned, operated, or held an interest in any licensed or registered facility that was the subject of proceedings which resulted in the discipline, suspension, denial, or revocation of the facility's registration or license?
☐ Yes ☐ No *If yes, provide a full explanation on a separate page.*

Has the applicant, MOR, or any owner or corporate officer owned, operated, or held an interest in any licensed or registered facility entered into a settlement agreement in resolution of a complaint resulting in the imposition of discipline on the facility's registration or license?
☐ Yes ☐ No *If yes, provide a full explanation on a separate page.*

Has the applicant, MOR, or any owner or corporate officer ever had:
1) any convictions related to the distribution of drugs (including samples);
2) any felony convictions;
3) any suspension(s) or revocation(s) or other sanction(s) by federal, state, or local governmental agency of any license or registration currently or previously held by the applicant or license for the manufacture, distribution, or dispensing of any drugs, including controlled substances, radiopharmaceuticals, and radioactive materials?

☐ Yes ☐ No *If yes, provide a full explanation on a separate page and attach a certified copy of each action and or court setting forth circumstances of such action(s).*

Has the applicant, MOR, or any owner or corporate officer ever been denied licensure by any federal or state agency including any state board of pharmacy?
☐ Yes ☐ No *If yes, provide a full explanation on a separate page.*

Is the applicant, MOR, or any owner or corporate officer the subject of pending disciplinary actions by a licensing/certification board located in the United States or any country or foreign jurisdiction?
☐ Yes ☐ No *If yes, provide a full explanation on a separate page.*

Has the applicant, MOR, or any owner or corporate officer ever voluntarily surrendered or resigned a professional license to a licensing/certification board in the United States or any country or foreign jurisdiction?

☐ Yes ☐ No *If yes, provide a full explanation on a separate page and attach a certified copy of each action and or court setting forth circumstances of such action(s).*

Affidavit (*must be signed and notarized)*

I certify under the penalties of perjury that I am the person authorized to sign this application and that all information provided is truthful, complete, and for lawful and honest purposes.

I, and my facility, to the best of my knowledge and belief, have filed all state tax returns and paid all state taxes required under law pursuant to M.G.L. c. 62C, § 49A.

I have read and understand all applicable state and federal statutes and regulations regarding the operation of the facility and will notify the Board in writing of any changes in ownership or management within thirty (30) days of such change(s).

I certify that the proposed Manager of Record has completed the continuing education requirements for the most recent two full calendar years.

I certify that each employed person has the education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law or regulation.

WARNING: In accordance with M.G.L. c. 94 § 13, the Board of Registration in Pharmacy may suspend or revoke a license or registration to distribute, dispense, or possess a controlled substance after a hearing pursuant to the provisions of Chapter 34A and upon finding that the licensee/registrant has furnished false or fraudulent information in any application filed under the provisions of Chapter 94C.

_____ _____

Name of owner, corporate officer, or MOR Title

_____ _____

Signature Date

Sworn and subscribed before me this _____ day of _____

Notary Public Signature _____My commission expires _____

NOTARY SEAL

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Controlled Substance Registration (CSR) Application
(MA Resident Facilities Only)

I hereby apply for a Controlled Substances Registration in accordance with M.G.L. c. 94C, § 7 with the associated **fee of $225**.

Name of Facility _____License No._____

Street Address _____

City/Town _____ State_____ Zip Code _____

Tel. No. _____ E-mail_____

FEIN No. _____ RCP License No. (nuclear pharmacy only): _____

Please check applicable controlled substance(s):

☐Schedule II ☐Schedule III ☐Schedule IV ☐Schedule V ☐Schedule VI**

**** Schedule VI: This substance is any prescription drug that has not already been included in Schedules II-V.**

Signature of Owner _____

Printed Name of Owner _____

TO BE COMPLETED BY BOARD

CHECK $_____DATE_____

CHECK NO. _____RECEIPT NO. _____APP NO. _____

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Attestation of Intent to Conduct COMPLEX Non-Sterile Compounding

All pharmacies are expected to engage in non-sterile compounding (except complex level) to meet the needs of the community to be served.

If a pharmacy does NOT plan to engage in any non-sterile compounding, a petition for waiver must be submitted for the Board's consideration.

All pharmacies licensed by the Massachusetts Board of Registration in Pharmacy (Board) that perform **complex non-sterile compounding** are required to prepare and dispense medications in compliance with state and federal laws and regulations, and all chapters of the United States Pharmacopeia (USP) including <795> *Pharmaceutical Compounding – Nonsterile Preparations* and <800> *Hazardous Drugs – Handling in Healthcare Settings*.

Complex non-sterile compounding: compounding of drug preparations which requires special training, special environment, special facilities or equipment, or the use of compounding techniques and procedures that may present an elevated risk to the compounder or the patient.
https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section39D
For more information on non-sterile compounding and examples of complex non-sterile compounds, please review the Board's *Advisory on Non-Sterile Compounding*.

As Manager of Record, I understand and attest under the pains and penalties of perjury that:

1. Employees engaged in or overseeing complex non-sterile compounding will be / have been trained in LEAN concepts, which are tools that assist in the identification and steady elimination of waste and promote continuous improvement in quality and efficiency, before a Complex Non-Sterile Compounding Pharmacy license may be renewed.

2. I have completed continuing education requirements for complex non-sterile compounding in accordance with Board regulations and that all pharmacy staff engaged in or overseeing complex non-sterile compounding have received the appropriate training and education required by law and regulation before engaging in compounding.

3. The pharmacy will only dispense medication pursuant to a valid prescription as defined in M.G.L. c. 94C, §19 for a single patient for any medications dispensed within or from Massachusetts.

4. If the pharmacy knows or should have reason to know that a compounded drug preparation dispensed into or from Massachusetts by the pharmacy is or may be defective in any way, the pharmacy shall immediately recall the drug preparation in accordance with M.G.L. c. 112, § 39D(e).

5. The pharmacy shall comply with all Massachusetts and federal laws and regulations governing the practice of pharmacy and USP <795> and USP <800>.

_____

Name of MOR

_____ _____

Signature Date

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Attestation of Intent to Conduct Sterile Compounding

All pharmacies licensed by the Massachusetts Board of Registration in Pharmacy (Board) that perform **sterile compounding** are required to prepare and dispense medications in compliance with state and federal laws and regulations, and all chapters of the United States Pharmacopeia (USP) including <797> *Pharmaceutical Compounding – Sterile Preparations* and <800> *Hazardous Drugs – Handling in Healthcare Settings*.

M.G.L. c. 112, § 39D defines **sterile compounding** as the engagement in the compounding of a sterile drug preparation. A sterile drug preparation is a compounded biologic, diagnostic, drug, nutrient or radiopharmaceutical, which under chapter <797> of the USP must be compounded using aseptic techniques. Sterile drug preparations may include, but are not limited to, implants, injectables, parenteral nutrition solutions, irrigation solutions, inhalation solutions, intravenous solutions, and ophthalmic preparations.
https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section39D

Will the pharmacy engage in non-sterile to sterile (i.e., high risk) sterile compounding? ☐ Yes ☐ No
***Please note that if any ingredient or component of a CSP was originally non-sterile, the final product must be considered high risk.

As Manager of Record, I understand and attest under the pains and penalties of perjury that:

1. Employees engaged in or overseeing sterile compounding will be / have been trained in LEAN concepts, which are tools that assist in the identification and steady elimination of waste and promote continuous improvement in quality and efficiency, before a Sterile Compounding Pharmacy license may be renewed.

2. I have completed continuing education requirements for sterile compounding in accordance with Board regulations and that all pharmacy staff engaged in or overseeing sterile compounding have received the appropriate training and education required by law and regulation before engaging in compounding.

3. The pharmacy will only dispense medication pursuant to a valid prescription as defined in M.G.L. c. 94C, §19 for a single patient for any medications dispensed within or from Massachusetts.

4. If the pharmacy knows or should have reason to know that a compounded drug preparation dispensed into or from Massachusetts by the pharmacy is or may be defective in any way, the pharmacy shall immediately recall the drug preparation in accordance with M.G.L. c. 112, § 39D(e).

5. The pharmacy shall comply with all Massachusetts and federal laws and regulations governing the practice of pharmacy and USP <797> and USP <800>.

_____

Name of MOR

_____ _____

Signature Date

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Hours of Operation

Name of Facility _____

Street Address _____

City/Town _____ State_____ Zip Code _____

Tel. No. _____ E-mail_____

Days	Open	Closed	Hours
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			
Total hours per week			

Describe how a patient may contact a pharmacist for questions or refill their prescription when the pharmacy is closed.

_____

Signature of MOR

_____ **Date**_____

Printed Name

Requirements for Certified Blueprints/Architectural Drawings

Drug Store Pharmacy	A **blueprint/architectural drawing** with the pharmacy outlined in **RED**, drawn to scale with the following items clearly labeled: 1. square footage* 2. prescription area 3. a legend explaining all abbreviations 4. patient consultation area 5. drop off and pickup windows 6. pick-up bins 7. refrigerator 8. safe 9. sink 10. designated non-sterile compounding area (draft 247 CMR 18.00 will require 10 square feet of counter space for non-sterile compounding) 11. other pertinent details ***** DO NOT include areas such as consultation rooms, front store area, offices, or restrooms in the proposed licensed square footage total.
Complex Non-Sterile Compounding Pharmacy	A **certified blueprint**** with the pharmacy outlined in **RED**, drawn to scale with the following items clearly labeled: 1. all requirements listed above for Drug Store Pharmacy 2. designated non-sterile compounding area, if applicable 3. the dedicated compounding room, including placement of containment hood(s) 4. detailed HVAC design plan and written description 5. hazardous drug storage area, if applicable 6. other pertinent details.
Sterile Compounding Pharmacy	A **certified blueprint**** with the pharmacy outlined in **RED**, drawn to scale with the following items clearly labeled: 1. all requirements listed above for Drug Store Pharmacy 2. designated non-sterile compounding area, if applicable 3. proposed pharmacy layout outlined in red, include square footage of each room 4. location and ISO classification of each primary and secondary engineering control 5. air flow 6. room pressurization 7. detailed HVAC design plan and written description 8. location of any pass-throughs 9. hazardous drug storage area, if applicable 10. other pertinent details.

**** All blueprints/architectural drawings must be submitted electronically.**
A certified blueprint must be stamped with an architect's seal along with the architect's signature.

Sterile Compounding Pharmacy Compliance

If the proposed design meets the listed requirement, please indicate by placing "Y" (yes) or "N" (no) and include comments as to the reason for the non-compliance and plans to mitigate. If not applicable, indicate with "NA".

Please note that this is not an all-inclusive list of proposed standards in Draft 247 CMR 17.00 or the requirements of USP. At a minimum, applicants are required to adhere to the standards set forth in the most recent version of USP <797> and USP <800>. It is the responsibility of the applicant to be familiar with the requirements set forth in USP chapters and the Board's regulations.

Draft 247 CMR 17.00	Citation	Y/N	Comments
Miscellaneous:			
A pharmacy may not compound non-sterile preparations in any Primary Engineering Control (PEC) or Secondary Engineering Control (SEC) used for sterile compounding.	17.03(8)		
A pharmacy shall have a dedicated changing area for sterile compounding personnel.	17.04(2)		
Primary Engineering Controls (PECs):			
A pharmacy shall utilize only commercially manufactured PECs.	17.06(1)		
All Secondary Engineering Controls (SECs):			
The doors leading into and between ISO Classified SECs shall be constructed with an interlocking design or utilize an alternative method to ensure that doors are not opened simultaneously.	17.07(1)(c)		
Unless prohibited by local building or fire code, an SEC may not have more than one door to immediately adjacent areas.	17.07(1)(b)		
Each newly constructed SEC shall allow for visual observation through windows or technology.	17.07(1)(a)		
SECs may not contain windows to the outdoors.	17.07(1)(k)		
A pharmacy shall ensure that any pass-through chambers: a. have an interlocking door design; and b. are not refrigerator units.	17.04(1)		
Walls shall be made of solid surface materials such as locking sealed panels or epoxy-coated gypsum board.	17.07(1)(j)		
Ceiling panels, fixtures, and other penetrations through the ceiling or walls shall be smooth and sealed around the perimeter.	17.07(1)(h)		
SECs shall utilize light fixtures designed for sterile compounding areas (i.e., cleanroom grade) that have an exterior surface that is smooth, mounted flush with the ceiling, and sealed.	17.07(1)(g)		
Sprinkler heads shall be recessed, covered, and easily cleanable.	17.07(1)(i)		
Floors shall be composed of wide sheet vinyl that is heat sealed at the seams, or other solid, smooth surface, and coved at the wall or appropriately sealed.	17.07(1)(l)		
SECs may not contain floor drains.	17.07(1)(f)		
A pharmacy may not locate a refrigerator in any ISO Classified SEC.	17.07(1)(e)		

A pharmacy may not use ISO Classified areas for drug storage.	17.04(3)		
Ante Rooms:			
A newly constructed ante room shall be at least 72 square feet.	17.07(3)(a)		
For hand hygiene, an anteroom shall have a stainless-steel sink that is located on the clean side of the line of demarcation at least one meter away from the buffer room door.	17.07(3)(b)		
The stainless-steel sink shall: i. be equipped with hands-free controls for water and soap dispensing; ii. have proper depth and capacity for hand washing up to the elbows; iii. minimize splashing and dripping of water; iv. be designed to prevent standing water; and v. have a faucet that does not have an aerator mechanism on the nozzle.	17.07(3)(c)		
An ante room shall have low-lint, disposable towels located in close proximity to the sink.	17.07(3)(d)		
Buffer Rooms:			
A newly constructed **non-hazardous drug** buffer room shall be at least 100 square feet.	17.07(2)(a)		
A newly constructed **hazardous drug** buffer room shall be at least 72 square feet.	17.07(2)(b)		
Buffer room doors shall be hands-free.	17.07(2)(c)		
HVAC			
Newly constructed ISO Classified SECs shall utilize a closed loop ducted system, a sealed plenum system, or equivalent HVAC design.	17.05(1)		
Supply air provided for each ISO Classified SEC shall be provided exclusively through ceiling mounted HEPA filters.	17.05(3)		
Air returns in ISO Classified SECs shall be mounted low on the walls	17.05(4)		
If utilized, relief air vents shall be mounted low on the wall and designed to prevent the ingress of less clean air or contaminants from adjacent areas.	17.05(5)		
Temperature/Humidity			
A pharmacy shall have a system to continuously measure the temperature and humidity of each SEC. The quantitative results shall be reviewed and documented at least daily on all days the pharmacy is open.	17.10(3)		
SECs shall maintain a temperature of 68 degrees Fahrenheit (20 degrees Celsius) or lower.	17.10(1)		
SECs shall maintain relative humidity of 60% or lower.	17.10(2)		